



WEEK ENDING NOVEMBER 14, 2014

OPP Weekly Activity Report

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BIOPESTICIDES & POLLUTION PREVENTION DIVISION

Biopesticides and Pollution Prevention Division (BPPD) Celebrates its 20th Anniversary On November 13, BPPD celebrated the 20th anniversary of the creation of the Division in November 1994 with a party that featured remarks by EPA leadership, recognition of the original "Charter" members of the group, entertainment, and a birthday cake for the Division. Several of the original Charter members that detailed to BPPD in 1994 returned for the event, as did employees who worked in the Division during the past 20 years and either retired or took other positions with the EPA or elsewhere. Worth noting were remarks made by Jim Aidala, who served as Deputy Assistant Administrator in 1994, and Janet Andersen, who was selected as the Division's first Director (1994 – 2009), about the origins of BPPD and the Pesticide Environmental Stewardship Program (PESP). OCSPP Assistant Administrator Jim Jones, OPP Director Jack Housenger, BPPD Director Bob McNally, and BPPD Deputy Director John Leahy also spoke. Entertainment highlights included "The Bob McNally Show," popular music from 1994, humorous awards to present BPPD employees, and film clips of sketches produced for the 10th anniversary of BPPD in 2004. The event was organized by a planning committee chaired by Sheryl Reilly, Special Assistant, and included Gina Burnett, Cara Finn, Linda Hollis, Elyse Lee, Gail Tomimatsu, Renae Whitaker, Jennifer Wingear, Judy Facey, and Kathleen Martin. (Michael Glikes, 703-305-6231)

ANTIMICROBIALS DIVISION

EPA Presents at Treated Wood Council Annual Meeting. On Thursday November 13, 2014, regulators from the Antimicrobials Division delivered a presentation and answered questions as part of a panel at the Treated Wood Council (TWC) annual meeting in Alexandria, VA. The presentation focused on the upcoming registration review of the heavy duty wood preservatives pentachlorophenol, creosote, and chromated arsenicals (e.g., CCA). EPA provided information on the differences between reregistration and registration review as well as information on data call-ins and benefits/alternatives. EPA completed its most recent reevaluation of the chemicals in 2008 when it issued its reregistration eligibility decisions. (Sandra O'Neill, oneill.sandra@epa.gov; Lance Wormell, wormell.lance@epa.gov)

EPA Participates in Site Visit to Ethylene Oxide Sterilization Facility. On Wednesday November 12, 2014 representatives from AD, PRD, HED, EFED, and BEAD traveled to Sterilization Services of Virginia in Richmond, VA to observe how products are treated with ethylene oxide (ETO). The hosts provided a walk-through of how the product flows through the facility and emphasized how worker and environmental exposure are minimized through engineering controls (e.g., fresh air full face respirators) and air scrubbers that remove ~99.5% of the ETO prior to release. The registered antimicrobial uses of ETO include the fumigation/sterilization of medical equipment, laboratory equipment, pharmaceutical, and aseptic packaging. The main conventional use of ETO is to

reduce microbials on whole and ground spices and other seasoning materials. (Donna Kamarei, 703-347-0443; Lance Wormell, 703-603-0523)



BIOLOGICAL & ECONOMIC ANALYSIS DIVISION

Interagency Agreement Finalized. The reimbursement Interagency Agreement (IA) between the Department of Homeland Security (DHS) and EPA has been finalized. MLB has been working with staff from ITRMD and IA Coordinator Rhonda Snoddy, Region 10, to complete the funding and accounting aspects of the IA. The IA has been sent to the EPA Cincinnati Finance Center for final processing. Under the agreement, EPA will offer expertise in the development of standard methods for testing high consequence viruses. This information will be relevant to OPP when evaluating the efficacy antimicrobial products on porous surfaces. The IA will be used to procure the services of a laboratory scientist through the ORISE program and to pay for materials and supplies. The total DHS funding to EPA for the two-year project, including overhead, is \$542K. (Stephen Tomasino, 410-305-2976)

Laboratory Holds Virucidal Efficacy Training for Department of Homeland Security Staff. MLB held a two-day training session for staff from the Department of Homeland Security's Plum Island Animal Disease Center (PIADC) on conducting the OECD Quantitative Method for Evaluating Virucidal Activity of Microbicides. In the near future, PIADC plans to launch a study utilizing the OECD method to identify a suitable surrogate virus for foot and mouth disease in efficacy evaluations. MLB currently conducts studies with feline calicivirus, one of the viruses that PIADC will evaluate as a possible surrogate. MLB is assisting PIADC with the development of the surrogate study plan, and the outcome of PIADC's research will be used to identify the appropriate surrogate virus for use in product registration for claims against foot and mouth disease. (J. Duncan, 410-305-2619 and M.Cottrill, 410-305-2955)



BEAD Meets with USDA, Weed Science Society of America, and Certified Crop Advisors on Herbicide Resistance Management. BEAD was joined by RD at the November 12 meeting which focused on the challenges associated with encouraging growers to use best management practices in their weed control programs. BEAD economist, Derek Berwald, presented an overview of ideas for

how OPP, using its expertise and data sources, might assess the economics of resistance management. One possibility is to gather information to carry out case studies on the consequences of resistance. Another possible project involved a case study of fungicide resistance where two states, Pennsylvania and New York, used difference approaches to promote resistance management. Follow-up activities will be discussed after a meeting on resistance that will be held at USDA on November 13. (Derek Berwald, 703-308-8115; Bill Chism, 703-308-8136; Jonathan Becker, 703-308-9434)

Herbicide Resistance Summit Follow-Up with USDA, Weed Science Society of America, and Certified Crop Advisors. On November 12, BEAD, RD, the OPP Director and Deputy Director met with WSSA, USDA/OPMP and CCA to discuss follow up to the Herbicide Resistance Summit that was held on September 10. OPP Director Jack Housenger gave a presentation on the Agency's approach to resistance management at the Summit. The WSSA indicated that EPA has taken important new steps to address resistance for herbicide-tolerant crops. They asked if the WSSA could provide additional assistance to EPA on resistance. The Office Director indicated that EPA welcomes suggestions from these organizations for dealing with resistance problems for herbicides going through registration review. (Yu-Ting Guilaran, 703-308-8200; Bill Chism, 703-308-8136; Jonathan Becker, 703-308-9434; Skee Jones, 703-305-7416)

BEAD Attends Annual Methyl Bromide Alternatives Outreach (MBAO) Conference. From November 4-6, 2014, BEAD biologists attended the 21st annual MBAO conference in Orlando, FL. Current research on soil and commodity/structure pest control was presented. Research included other fumigants as well as non-fumigant options to replace methyl bromide uses. There were also regulatory discussions, including California regulations and USDA quarantine. The research and discussions at this conference remain relevant to OPP as registration review of fumigants has begun. (Colwell Cook, 703-308-8146; Bill Chism, 703-308-8136)

INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

<div>  OPP FOIA Request Status Report for Nov. 3- 7, 2014  </div>							
Requests Received		Requests Closed			Requests Open		
FY15	This Week	FY15	FYTD	This Week	FY15	Prior Years	Total
66	8	16	51	10	50	320	370

(Ana Espinoza, 703-347-0102)

List of Disinfectants for Ebola Updated. The ITRMD Web Team worked with AD to update the Disinfectants list for Ebola. New products were added. Please see [Disinfectants for Use Against the Ebola Virus](#) for more information. (Miriam Organic, 703-605-0583)

List of Applicators Certified Under the EPA Plan Updated. The ITRMD Web Team worked with FEAD to update the listings for certified private and commercial pesticide applicators in Indian Country. The lists of applicators are current as of November 10, 2014. Please see [Applicators Certified under the EPA Plan](#) for more information. (Miriam Organic, 703-605-0583)

Technical Briefing on Registration of Enlist Duo Herbicide Updated. The ITRMD Web Team worked with FEAD to update the [Technical Briefing on Registration of Enlist Duo Herbicide](#) document. An updated version of the PDF was posted. (Miriam Organic, 703-605-0583)

ENVIRONMENTAL FATE & EFFECTS DIVISION

EFED Presents at SETAC North America Annual Meeting. During the 35th Annual Society of Environmental Toxicology and Chemistry (SETAC) meeting, Kris Garber discussed two approaches that EFED/OPP uses to assess risk of pesticides to birds: the risk quotient approach and the probabilistic approach. Garber pointed out that the risk quotient method independently considers conservative exposures to birds through diet, drinking water, inhalation, and dermal contact. In contrast, the probabilistic approach, using the Terrestrial Investigation Model, integrates these exposure routes and considers movement of birds in and off the treated fields as well as a range of sensitivities in individual birds. At the same meeting, Melissa Panger gave a presentation on the progress that EPA, USDA, the US Fish & Wildlife Service, and the National Marine Fisheries Service have made in implementing the recommendations that the National Research Council (NRC) made on several scientific issues associated with determining the risk of pesticide registration and use to listed species protected under the Endangered Species Act. The NRC provided the agencies with recommendations that included but were not limited to approaches to probabilistic methods, weight-of-evidence analysis, mixtures, sub-lethal effects, geospatial data sets, refinements to aquatic and terrestrial exposure characterization, and population modeling. (Kris Garber, 703-347-8940; Melissa Panger, 703-305-6136; Edward Odenkirchen, 703-305-6449).

REGISTRATION DIVISION

RD Attends American Society of Tropical Medicine and Hygiene (ASTMH) Meeting
On November 2-6, 2014, Kevin Sweeney/Invertebrate-Vertebrate Branch1 (IVB1) attended the 63rd Annual Meeting of the ASTMH in New Orleans, Louisiana. The ASTMH is a worldwide organization of scientists, clinicians and program

professionals whose mission is to promote global health through the prevention and control of infectious and other diseases that disproportionately afflict the global poor. Sweeney made an invited presentation to the American Committee on Medical Entomology on EPA topics of relevance to medical entomologists generating efficacy data for pesticide registration. Some of the topics discussed were GLP (Good Laboratory Practice), approaches to data development that may generate acceptable data for use in registration, product performance levels, the human subject testing rule, and pre-registration consultations for new products. ASTMH Meeting highlights included:

- **Bill Gates of the Bill and Melinda Gates Foundation** who was the Keynote Speaker. His speech emphasized the challenges associated with eliminating malaria. His personal goal is to end malaria in his lifetime.
- **Developing new pesticides and related tools to combat insecticide resistance.** Currently, only four classes of insecticide are used in most vector control programs. Many of these programs have returned organophosphate [pirimiphos methyl – sold as Syntenta’s Acetellic 50 EC for indoor residual spraying (IRS)] and carbamate [bendiocarb – sold as Bayer’s Ficam] insecticides back into their portfolio due to resistance to DDT and pyrethroids. Chlorfenapyr [sold as BASF’s Phantom] has been tested extensively but has not received a WHO vector control recommendation yet. The Integrated Vector Control Consortium (IVCC) has identified four new insecticide classes for use in vector control and they are hopeful of at least three making it through the developmental and regulatory processes.
- **Outdoor transmission of vector-borne diseases** is common in the US but has been much less important than indoor transmission in the rest of the world due largely to mosquito and human behaviors. With the success of many indoor control interventions such as IRS, bed nets, and mosquito coils; mosquito vectors exhibiting extrinsic biting behavior and preference for day/evening biting are becoming more important with control methods sought. Passive community level interventions are preferred and insecticide/repellent-treated clothing, spatial repellents, outdoor residual insecticide treatments, and push-pull scenarios to include Attractive Toxic Baits (ATBs) are of greatest interest. Revival of outdoor space-spraying may occur. These use patterns are already widely used in the US and are all EPA-registered. (Kevin Sweeney, 703/305-5063)

Registration Division QA/QC and PPLS Upload of Electronic Labels On November 2-8, 2014, **56** product labels from RD were uploaded to PPLS. Recently, RD adopted a new e-label process division-wide in which electronic labels and letters are e-stamped and e-signed, QA/QC of the documents are performed within the division, and the letters and labels are automatically uploaded onto PPLS twice a day. Thirty-two of the labels were automatically uploaded to PPLS

via the new electronic process, while 24 labels were scanned; then uploaded to PPLS by contractors. Over the course of the week, RD's QA/QC Team reviewed 43 electronic decision letters/labels. The QA/QC team consists of members from each product branch (Mindy Ondish/HB; Aswathy Balan/FHB, Maryam Muhammad/FB, Jennifer Gaines/IVB1; Carlyn Petrella/ IVB2; and Jacquelyn Marchese/IVB3). (Jennifer Urbanski, 703/347-0156; Shaunta Hill, 347-8961)

The Organisation for Economic Co-operation and Development (OECD) Expert Group Meeting

On November 6-7, 2014, John Redden of the Chemistry, Inerts and Toxicology Assessment Branch (CITAB) attended the OECD Expert Group Meeting on Eye Irritation/Corrosion in Paris, France. The proposal for an IATA (integrated approach on testing and assessment) for eye irritation and corrosion was accepted by the Expert Group. Dr. Joao Barroso of EURL (European Union Reference Laboratory)-ECVAM (European Centre for the Validation of Alternative Methods) agreed to co-lead the project with the US. The timeframe for completion is three years. Dr. Chantra Eskes, vice president of ESTIV (European Society of In Vitro Toxicology) requested that the US review the Ocular Irritation test method to determine if the method used be recommended as a Test Guideline. Dr. Barroso generously agreed to help with the proposed Cytosensor Guideline and stated that the issue of US and GHS (Globally Harmonized System of Classification and Labelling of Chemicals) also should be explored in the proposed Guidance Document which the Agency has committed to reduction of pesticide testing using animals. (John Redden, 703/305-1969)

OPP Provides Input to USDA's Huanglongbing Multi-Agency Coordination System (MAC)

On November 7, 2014, OPP provided input to USDA on three different grant submissions that they were evaluating to fight citrus greening disease in Florida. Specifically, USDA is looking to fund shovel-ready projects and they were asking OPP to provide input on whether there were significant regulatory hurdles that could cause problems if any of the projects moves through to implementation. (Gail Tomimatsu, 703/308-8543; Susan Jennings, 706/355-8574)

Registration Division's Risk Assessment/Risk Management LEAN Team On November 10-14, 2014, staff members from the Fungicide Branch and the Invertebrate-Vertebrate Branch 3 participated on the LEAN team tasked with improving the risk assessor and risk manager interaction for registration review. The team consisted of 11 members from RD, EFED, HED, PRD, and BEAD. The goal of the team was to create more consistent, defensible, protective, and enforceable pesticide risk management decisions that are more timely and less resource-intensive. The team identified opportunities to improve the structure, efficiency, consistency, timing and outcomes of the risk assessment and risk management process. For registration review actions, the team estimates that there will be a **19%** reduction in total process time for typical actions and a **78%**

reduction in total process time for actions that can be routed through a more simplified process. (Heather Garvie, 703/308-0034; Mark Suarez, 305-0720)

LEAN Effort on Creation, Maintenance, Storage, and Retrieval of Registration

Jackets RD staff (Aswathy Balan, Rachel Holloman, Maggie Rudick, and Steve Schaible) were members of a LEAN team who met on November 10-14, 2014 to look at the current process for paper “jackets” and “jackets” in an electronic realm. Currently, the regulatory history of a pesticide product resides in a paper jacket, or in some cases, as a scanned “e-jacket” in OPPIN. Some drawbacks to this paper jacket include that it is:

- Only accessible to one person at a time
- In paper form
- Not easily searchable
- Requires physical transfer to and from the 4th floor file room at numerous points in the review process
- Requires scanning resources for e-jackets and FOIA requests

This LEAN team included representation from ITRMD, OEI, and the four risk management divisions in OPP (AD, BPPD, PRD, and RD). It was led by Andrew Cox (ITRMD) and sponsored by Mark Hartman (acting ITRMD Division Director). The team started the week by mapping out the current flow of a paper jacket associated with a section 3 new product registration application. Through fact finding “field trips” and expert interviews with FOIA staff, OGC, HED electronic database experts, the 24(c) team leader and ACE contractors involved with the 24(c) special local need electronic submission pilot, and the LEAN front-end processing team, the group gained a thorough understanding of the current paper process and opportunities for improvement by moving this process to electronic. Near-term streamlining opportunities were identified for applications received in paper, and an implementation plan was developed to pilot a virtual jacket process for applications currently submitted electronically. Under this pilot, applications received electronically would not be printed to paper but would stay electronic through the review process. All elements of the EPA review that are normally added to the jacket would instead be saved as electronic files to a central repository—associated with the submission, product, and active ingredient through meta data—and would be accessible by query. Looking further out, the group mapped out a process for integrating the virtual jacket effort with ongoing efforts of Workgroup I and the other LEAN groups to receive applications electronically through a web-based portal and manage these through an electronic workflow process. (Steve Schaible, 703/308-9362)

Phase IV of Crop Group Project Publishes in the Federal Register On November 14, 2014, the Notice of Proposed Rulemaking (NPRM) for the fourth phase of an ongoing initiative within OPP, the crop grouping revisions project, published in the *Federal Register*. This rule proposes to revise the crop group regulations in 40 CFR 180.41 by revising the existing leafy vegetable (except brassica) and brassica

vegetable crop groups and by establishing the following new crop groups: stalk, stem, and leaf petiole; tropical fruit, edible peel; and tropical fruit, inedible peel. This NPRM also proposes to revise 40 CFR 180.40(f). EPA expects these revisions to promote greater use of crop groupings for tolerance-setting purposes and, in particular, will assist in making available lower-risk pesticides for minor crops, both domestically and in countries that export food to the United States. This is the fourth in a series of planned crop group updates we expect to propose, and is the second phase that the Registration Division's Minor Use Team has held the rule-writing responsibilities associated with the project. (Barbara Madden, 703/305-7390) [Further information about the specific crop grouping revisions, including the proposed and final rules published to date and the supporting and related material, may be found at [regulations.gov](http://www.regulations.gov) in public docket: EPA-HQ-OPP-2006-0766]

Association of American Pesticide Control Officials (AAPCO) Pollinator Meeting

Marietta Echeverria (RD) and Michael Goodis (PRD) participated in a pollinator committee meeting hosted by Steve Dwinell representing the American Association of Pesticide Control Officials (AAPCO). In response to OPP's request to partner with state and tribal co-regulators on the development of pollinator protection plans, Steve Dwinell (AAPCO) convened a committee to collect information about implemented pollinator protection plans and activities planned to develop them. Five states have implemented plans and an additional 20 are working toward plan development. The committee also discussed lessons learned and other factors that EPA and states should consider as we move forward with pollinator protection plans. (Marietta Echeverria, 703/305-8578)

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Chemical	Company	Registration Number	Action Code*	Due Date	Response Date
The Fungicide Herbicide Branch granted:					
Tribufos	Loveland Products, Inc.	34704-867	R340	3/18/2015	11/12/2014
Erick Kraft, 703/308-9358					
Flumioxazin	Axion AG Products, LLC	89167-45	R300	11/21/2014	11/10/2014
Sarah Meadows, 703/347-0505					
The Herbicide Branch granted:					
Glyphosate-isopropylammonium	CropSmart, LLC	85945-1	R300	12/1/2014	11/13/2014
Propanil	Pronil, LLC	90188-2	R301	12/8/2014	11/10/2014
Shanta Adeeb, 703/347-0502					
MCPB, sodium salt	NuFarm, Inc.	71368-5	R350	11/6/2014	10/30/2014
Bethany Benbow, 703/347-8072					
Indaziflam	Bayer Environmental	432-1539 432-1540	R300	11/24/2014	11/5/2014
Maggie Rudick, 703/347-0257					
The Invertebrate-Vertebrate Branch 3 granted:					
Amitraz	Merial Limited	65331-7	R340	11/10/2014	11/10/2014
Autumn Metzger, 703/305-5314					

PRIA Categories

R300 – New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation or selective data citation where applicant owns all required data or submits specific authorization letter from data owner; category also includes 100% repackaging of registered end-use or manufacturing-use product that requires no data submission or data matrix [\(3\)](#) [\(4\)](#); **R301** – New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner [\(2\)](#) [\(3\)](#); **R340** – Amendment requiring data review within RD (e.g., changes to precautionary label statements) [\(2\)](#) [\(3\)](#); and **R350** – Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement) [\(2\)](#) [\(3\)](#).

HEALTH EFFECTS DIVISION

HED Participates in OPP Paraquat Team Meeting: Several HED staff members participated in this week's Paraquat Team Meeting. The discussion focused on finalizing the educational document on paraquat ingestion risk. This was developed jointly by FEAD and HED and is being reviewed by the paraquat team and managers. This educational piece is intended to supplement certified applicator recertification coming up this winter. It will serve as a poignant reminder to all applicators not to transfer paraquat or any pesticide into a beverage container. Once final, FEAD will circulate the educational piece to all national stakeholders involved with certified applicator training, including The American Association of Pesticide Safety Educators (AAPSE) and the Certification and Training Assessment Group (CTAG). Trainers will be able to fold this important message into the recertification curriculums. One swallow can kill! (Elizabeth Evans, 305-7891)